condition selected from the group consisting of MS, a pro-MS immune response, and a combination thereof; in providing an additional parameter to a competent health professional in making a medical opinion.

The term "pro-MS immune response" is used herein, for purposes of the specification and claims, to mean a humoral immune response induced against an epitope comprising a terminal alpha 2,6-linked sialic acid (e.g., comprising sialyl Tn or sTn which comprises a terminal sialic acid alpha 2,6-linked to GalNac) of a shed antigen (glyco-molecule), resulting in production of IgG antibody against the epitope ("anti-α(2,6)NeuAc Ab"), and complexes comprised of the shed antigen comprising the epitope complexed to anti-α(2,6)NeuAc Ab, and may further comprise one or more members of the sialoadhesin family; wherein the shed antigen is released or produced particularly in relation to CNS tissue damage characteristic of MS during the MS disease process. In a preferred embodiment, the resultant complexes bind to and induce Fc receptor-expressing cells (e.g., one or more cell types selected from the group consisting of granulocytes, macrophages, microglia, activated mast cells, astrocytes, oligodendrocytes) which results in the release of inflammatory mediators (e.g., cytokines and/or tissue degradative enzymes) which may promote (contribute to) CNS tissue damage characteristic of MS (e.g., demyelination and plaques characteristic of MS). A similar immune response, a pro-tumor response, has been described in U.S. Patent No. 6,251,616 (the disclosure of which is herein incorporated by reference). In a preferred embodiment, the anti-α(2,6) NeuAc Ab is induced by a shed

antigen comprising glycolipid, as previously described herein in more detail. Cellular markers for a pro-MS immune response have been described in detail in U.S. application Serial No. 60/150256, now abandoned, the disclosure of which is herein incorporated by reference.

The term "biological assay conditions" is used herein, for purposes of the specification and claims, to mean those conditions under which an affinity ligand can specifically bind to the molecule for which it has binding specificity (e.g., a component of the sialocomplexes according to the present invention). As known to those skilled in the art, such conditions may include one or more of: a pH range of from about 5 to 9, ionic strengths such as that ranging from distilled water to about 1 molar sodium chloride, and a temperature in the range of from about 4°C to about 45°C; and may further include a time sufficient for binding to occur (e.g., in a range of from about 10 minutes to about 2 hours).

There is a need for clinical tests which can aid in the diagnosis of MS. Additionally, there is a need for clinical tests which can detect one or more of: individuals at risk of developing MS, initiation of inflammatory processes preceding development of a pattern of clinical symptoms characteristic of MS, detection of MS at an earlier point in time than currently available techniques, and monitoring the progression of MS (e.g., from RRMS to SPMS). Further, presently there are no commercially available tests to evaluate for the presence of a pro-MS immune response. There is a need for laboratory tests that distinguish